USER MANUAL

EASYFLOW5
Oxygen Concentrator

Model: PM4300 Series

(PM4351 Shown)

SAVE THESE INSTRUCTIONS

℞ ONLY

Federal (USA) law restricts this device to sale by or on the order of a physician.

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For latest revision of this User Manual, go to
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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *PM4300 Series Oxygen Concentrator* from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Precision Medical, Inc. *Stationary Oxygen Concentrator* is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

READ ALL INSTRUCTIONS BEFORE USING

This manual is provided for your safety and to prevent damage to the *Oxygen Concentrator*. If you do not understand this manual, DO NOT USE the Concentrator and contact your Provider.

⚠DANGER

This product is not intended as a life-sustaining or life-supporting device.

EXPLANATION OF ABBREVIATIONS

l/min	Liters Per Minute
LED	Light Emitting Diode

SAFETY INFORMATION - WARNINGS AND CAUTIONS

DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

PM4300 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1

Caution! U.S. Federal Law restricts this device to sale by or on the order of a physician.

CONSULT ACCOMPANYING DOCUMENTS

IPX1 Degree of protection against ingress of liquids

General Mandatory Action Sign

Class II Equipment

Type BF Equipment

General Alarm

Alternating Current

Power ON

Power OFF

NO SMOKING

Dangerous Voltage

NO Oil or Grease

DO NOT Disassemble

⚠DANGER

- **DO NOT** smoke, allow others to smoke or have open flames near the Concentrator when in use.
- **DO NOT** use near any type of flame or flammable/explosive substances.
- **DO NOT** allow Concentrator to exceed “Operating or Storage Temperature Specifications”.
- The Concentrator is not suitable for use in the presence of flammable anesthetic.

TO REDUCE THE RISK OF ELECTRICAL SHOCK:

- **DO NOT** use while bathing.
- **DO NOT** reach for a Concentrator that has fallen into water. Unplug immediately!
- **DO NOT** attempt to repair Concentrator. Any attempt could result in electrical shock.

⚠WARNING

- Use the Concentrator for its “Intended Use” as described in this manual.
- In the event of an equipment audible alarm or if you are experiencing any signs of discomfort, connect to another source of oxygen and contact your Provider and/or Health Care Professional immediately.
- In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this Concentrator.
- Where the prescribing Health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternative source of oxygen should be available for immediate use.
- **ALWAYS** keep the Concentrator in an upright position.
- **ALWAYS** keep at least 6 in. (15.24 cm) away from walls, furniture, and especially curtains that could prevent adequate airflow to the Concentrator.
- **DO NOT** place the Concentrator in a small closed space such as a closet.
- **DO NOT** use extension cords or electrical adapters.
- The Concentrator is designed to operate with a single lumen, adult cannula.
- Flow is available ONLY at the listed settings. There is NO FLOW between settings.
- ***Flow Setting Knob does not rotate 360*** **degrees.**

TO REDUCE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS:

- Keep the Concentrator away from heat or open flame.
- **DO NOT** use if Concentrator has a damaged power cord or plug.
- **DO NOT** use if Concentrator has been dropped or damaged.
- **DO NOT** use oil or grease on the Concentrator.
- **DO NOT** cover the air vents, the Concentrator requires proper ventilation.
- **DO NOT** remove the cover on the Concentrator. Servicing must be performed by a trained professional.

CAUTION
DO NOT place any liquids on or near the Concentrator. If any liquid gets on or in the Concentrator, immediately turn “OFF” the power switch, unplug from the electrical outlet and contact your Provider .

SPECIFICATIONS

Dimensions:

Length:	17.1 in	(43.5 cm)
Width:	12.3 in	(31.1 cm)
Height:	17.0 in	(43.2 cm)

Weight: 29.6 lbs (13.4 kg)

Shipping Weight: 33.9 lbs (15.4 kg)

Altitude*: Sea Level to 10,000 ft (3,048 m)

Operating Temperature: 50˚F to 95˚F (10˚C to 35˚C)

Storage/ Transport Temperature: -29˚F to 140˚F (-34˚C to 60˚C)

Operating / Storage / Transport

Relative Humidity: Up to 95% Non-condensing

Outlet Pressure: 8.0 psi ±10%

Oxygen Concentration and Flow Tolerance:

**Altitude*	*Flow Tolerance (l/min)*	*Oxygen %*
Up to 6,500 ft	± 10% of settings 2 - 5 ± 200 ml settings 0.5 -1.5	87 - 95 %
6,501 - 10,000 ft	± 20% of settings 1 - 5 ± 200 ml settings 0.5	85 - 90 %

When checking the concentrator’s performance, the oxygen analyzer used should comply with ISO 21647 standard.

Start up time: 87% O_2 Concentration ≤ 3 min

Electrical (AC Power): 115 VAC ±10%, 60 Hz, 3.2 Amps; 350 Watts

Tubing Limitations: 7 ft cannula with a maximum 40 ft of Crush-Proof Tubing (47 ft total).

Equipment Classification:

Class II - with respect to protection from electrical shock

Type BF - degree of protection against electrical shock

IPX1 - degree of protection against ingress of liquids

Mode of Operation - Continuous

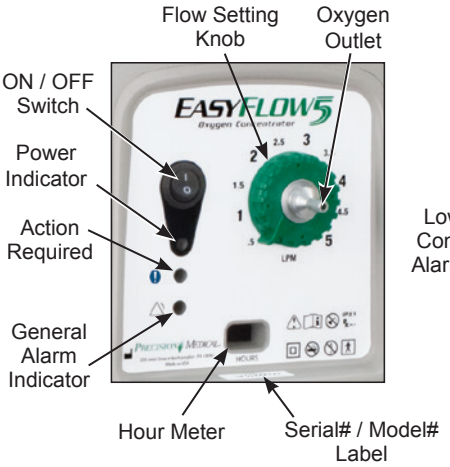
This Concentrator meets the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4 and Safety Requirements for ISO 8359.

Specifications are subject to change without prior notice.

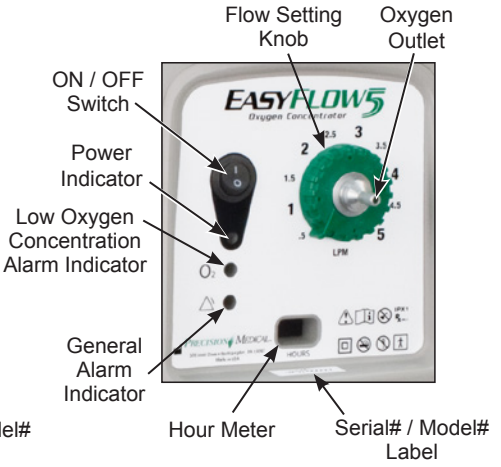
COMPONENT DESCRIPTION

⚠CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.



Model PM4350



Model PM4351

Back & Side View

PM4351 shown

Front View

OPERATING INSTRUCTIONS

⚠WARNING

- Read this User Manual before operating the Concentrator.
- Additional monitoring or attention may be required for patients using this Concentrator who are unable to hear or see alarms or communicate discomfort.

CAUTION

- Inspect the Concentrator for visual damage before use, DO NOT USE if damaged.
- To prevent damage to the Concentrator, DO NOT operate the Concentrator without the inlet filter.

1. Place the Concentrator in a location where room air can be drawn in without being restricted.

   NOTE: *There must be at least six (6) in. (15.24 cm) of space around the Concentrator when operating.*

2. Plug the power cord into an electrical outlet.

   NOTE: *The Concentrator is equipped with a polarized plug (one blade is wider than the other). As a safety feature, this plug will fit in a polarized outlet only one (1) way. If the plug does not fully fit in the outlet, reverse the plug. If it still does not fit, contact a qualified electrician. DO NOT attempt to defeat this safety feature.*

To use without a bubble humidifier:

3. Attach the Cannula to the Oxygen Outlet.

To use with a bubble humidifier:

3. Attach humidifier adaptor to Oxygen Outlet, fill the bubble humidifier bottle and connect as per bubble humidifier instructions.

   NOTE: *• Be sure not to cross thread, this may cause a leak.*
   • Concentrator can be used with or without Humidifier.

   3a. Attach the Cannula to the bubble humidifier bottle.

4. Push the Power On/Off (I /O) switch to "ON" (I) position. The Power Indicator light below the On/Off (I /O) switch will illuminate green when the Concentrator is powered ON.

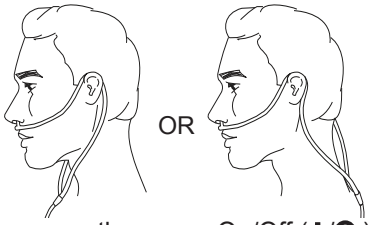
   NOTE: *If there is no electrical power or the device has not been plugged into the electrical outlet correctly, turning the Concentrator "ON" will cause an Audible Alarm for up to two (2) minutes.*

5. Set the flow to the prescribed setting by turning the flow setting knob on the Concentrator to the prescribed flow.

   NOTE: • There is NO FLOW between settings. The Flow Setting Knob must point to a specific number in order to obtain flow.
   • Flow Setting Knob does not rotate 360 degrees.

6. Oxygen should be flowing through the cannula. If it is not, refer to the "ALARM / INDICATORS / TROUBLESHOOTING".

7. Place the cannula over your ears and position the prongs in your nose as instructed by your Provider or cannula manufacturer.



8. When the Concentrator is not in use, press the power On/Off (I /O) switch to "OFF" (O) position.
9. Unplug Concentrator from electrical outlet for complete disconnection from Power Source.

ALARM / INDICATORS / TROUBLESHOOTING

The Audible Alarm and LED Indicators are listed in the chart below.

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
When device is turned "ON", device does not function and the GREEN Power Indicator does not light.	Continuous	Concentrator is not properly plugged into electrical outlet.	Make sure Concentrator is properly plugged into the electrical outlet.
RED General Alarm Indicator is "ON" steady or continuously blinking; device stops functioning.	Repeated beeping	System malfunction.	Turn power switch "OFF" and wait 5 minutes, then turn back "ON". If condition persists, turn the concentrator "OFF", connect to another source of oxygen and contact your Provider.
RED General Alarm Indicator flashes once, device momentarily stops functioning, then automatically restarts.	Single beep	Momentary AC power interruption.	It is normal for this to occur occasionally (such as during severe weather); however, if this condition persists, connect to another source of oxygen and contact your Provider.
GREEN Power Indicator is "ON", YELLOW Oxygen Concentration and RED General Alarm Indicators are flashing and device is running	Repeated beeping	Device overheating	Internal temp above 109° Move Concentrator to a cooler location. Ensure Concentrator is positioned away from curtains or drapes, hot air registers or heaters. Be certain to place the Concentrator so all sides are at least 6 in. (15.24 cm) away from a wall or other obstruction. DO NOT place concentrator in a confined area.

Continued on next page.

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
RED General Alarm Indicator is flashing while beeping, device stops functioning.	Repeated beeping	Device overheating	Move Concentrator to a cooler location. Ensure Concentrator is positioned away from curtains or drapes, hot air registers or heaters. Be certain to place the Concentrator so all sides are at least 6 in. (15.24 cm) away from a wall or other obstruction. DO NOT place concentrator in a confined area.
(PM4351 ONLY) YELLOW Oxygen Concentration Indicator is "ON" steady.	None	Low oxygen concentration.	Continue to use concentrator, but contact your Provider.
(PM4351 ONLY) YELLOW Oxygen Concentration and RED General Alarm Indicators are "ON" while beeping; device stops functioning.	Repeated beeping	Very low oxygen percentage.	Turn the concentrator "OFF", connect to another source of oxygen and contact your Provider.
No flow from nasal cannula.	None	1. Kinked tubing. 2. Nasal cannula has become disconnected from oxygen outlet on concentrator or from extension tubing. 3. Connection between bubble humidifier and oxygen outlet on concentrator has become loose.	1. Check tubing and nasal cannula for kinks. 2. Check cannula and tube fittings for proper connection. 3. Tighten bubble humidifier bottle.
Limited or no oxygen flow.	None	Dirty or obstructed bubble humidifier, or leak present.	Remove the bubble humidifier bottle and if flow is restored, clean or replace the bubble humidifier.
Condensation collects in the oxygen tubing when you use a bubble humidifier bottle.	None	Concentrator not properly ventilated, elevated operating temperatures.	Ensure Concentrator is positioned away from curtains or drapes, hot air registers or heaters. Be certain to place the Concentrator so all sides are at least 6 in. (15.24 cm) away from a wall or other obstruction. DO NOT place the Concentrator in a confined area. DO NOT OVERFILL bubble humidifier. Allow the oxygen tubing to dry out, or replace with new tubing.

MAINTENANCE / CLEANING

⚠WARNING
DO NOT remove cover or attempt to repair. There are no user serviceable parts inside. Contact your Provider for repairs.

1. Patient should connect to an alternate Oxygen source.
2. Turn the Concentrator to the “OFF” (O) position.
3. Unplug the Power Cord from electrical outlet.
4. Clean exterior surfaces of the Concentrator with a cloth dampened with water and mild detergent.
5. Wipe the Concentrator dry with a clean cloth.
6. When not in use, store the Concentrator in a clean area free from grease, oil and other sources of contamination.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

DISPOSAL INSTRUCTIONS

This device may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.

REPLACEMENT PARTS

DESCRIPTION	PART#
Humidifier Adapter	507324

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Visit us at www.precisionmedical.com

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Oxygen Concentrator, (the Product), will be free of defects in workmanship and/or material for the following period:

Oxygen Concentrator *three (3) years from date of purchase*

Precision Medical, Inc. is NOT responsible for normal wear and tear, or any neglect or abuse of the product.

Precision Medical, Inc. is NOT responsible for the shipping cost of the repair.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representatives of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

506767 Rev2 03/13 Printed in USA